201-15434

Don Lederer, CHMM
Product Steward
Solutia Inc
575 Maryville Centre Drive
St. Louis, Missouri 63141

P.O. Box 66760
St. Louis, Missouri 63166-6760
Tel 314-674-1113
Fax 314-674-8808
dalede@Solutia.com

July 6, 2004

Mr. Mike Leavitt, Administrator
U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116
Attn: Chemical Right-to-Know Program

RE: **HPV Chemical Challenge Program**
Response to Comments
AR-201-14674
Terphenyls, Partially Hydrogenated
CAS Number 61788-32-7

Dear Administrator Leavitt:

We are pleased to provide the Agency our responses to comments received from EPA and other stakeholders on our referenced HPV Chemical Challenge submission for the Terphenyls, Partially Hydrogenated, which you will find attached. We are forwarding responses to the specific comments, along with a revised Test Plan and Robust Summary.

Thank you for your consideration. Please contact me directly should there be any question related to this submission.

Sincerely,

Donald A. Lederer, CHMM
Product Stewardship Manager

Response to Comments on HPV Challenge Submission

Terphenyls, Partially Hydrogenated

CAS Number 61788-32-7

EPA Comments

Comments related to the Test Plan

COMMENT 1: *Stability in water*. The submitter needs to incorporate a technical discussion explaining why this chemical is stable in water in the robust summary.

RESPONSE: A technical discussion based on reaction thermodynamics has been included in a revised and expanded robust summary for water stability. This has also been noted in the test plan.

COMMENT 2: *Biodegradation*. On page 11, the submitter indicates that "while not Readily Biodegradable, significant biodegradation has been established in inherent biodegradation studies (SCAS and River Die Away)." EPA believes that this statement is potentially misleading. The SCAS test, although an OECD inherent biodegradability test, is considered the most powerful of all standard biodegradation tests and provides an optimal environment for biodegradation to occur. The result obtained--35%--is quite low for this type of test. Given this and the nature of the SCAS test, the results do not give any indication about the biodegradability of this chemical under environmental conditions. In the River Die-Away test, the duration of the test (50 days) renders the results obtained (68% degradation) of uncertain value at best, relative to the chemical's biodegradability in the environment, since the characteristics of natural water can be expected to change significantly in this period after the water is brought into the laboratory. The submitter needs to change the conclusions on the biodegradation and indicate that, while not readily biodegradable, the results of these tests support the conclusion that the test substance is eventually biodegradable.

RESPONSE: We have changed the test plan conclusions accordingly. The following conclusion was added to the robust summaries: “The material displayed biodegradation sufficient to conclude that it would not be persistent in the environment.”

COMMENT 3: *Fugacity*. The submitter used default values as inputs when running its fugacity model. The use of estimated values introduces uncertainties that then become

magnified in modeling applications. The submitter needs to use the measured physicochemical values reported in the robust summaries as inputs into the model.

RESPONSE: As explained in the test plan, use of actual data from an undefined mixture such as the commercial products for which Solutia has actual data, is inappropriate for modeling, as distribution in the environment is dependent upon the physico-chemical properties of each individual component.

The fugacity model was run using the structure of 1,3-dicyclohexylbenzene as a surrogate chemical. This substance is believed to be a significant component of the mixture. Solutia has no measured values for this surrogate substance. Model-generated parameters were used for the fugacity calculation but all were checked to assure they were in accord with the known properties of the mixture. Physico-chemical data for pure 1,3-dicyclohexylbenzene are not available for use. Data from the variable mixture is inappropriate – for example the melting point of the mixture is expected to be lower ("depressed") because of the well-known freezing-point depression effect.

As most of the components are thought to have similar structures, the presented distribution data is considered representative. An explanatory remark was added to the robust summary to avoid future confusion. The robust summary was moved from "transport" to "distribution" to allow inclusion for sediment value and proper "level 3" designations.

The robust summary for indirect photolysis was inadvertently omitted from the original submission. A robust summary for this end point has been added.

COMMENT 4: *Developmental toxicity*. The submitter needs to correct the omission of the developmental toxicity endpoint and provide a separate robust summary with the developmental effects from the two-generation reproductive toxicity study.

RESPONSE: A robust summary for the guideline (OECD 414) developmental study was prepared and added to the IUCLID. Regarding the two-generation study, the amount of test substance that the females were exposed to, based on the target concentrations of test substance in feed and average feed consumptions, were only 2.5, 8.3, 20.4 and 81.2 mg/kg-day. Even with increased feed consumption of the pregnant dams, it is doubtful that the test substance exposure reached the low dose level (125 mg/kg-day) of the definitive developmental toxicity study. Because of this, and the lack of effects the developmental data from the two-generation study are not presented. Instead, a remark has been added to the developmental toxicity robust summary noting the lack of developmental effects and the test-substance exposure level.

A new section (5.0) on developmental toxicity has also been added to the test plan and the developmental toxicity results included in the tables.

COMMENT 5: In Table 1 on page 9, symbol "-", not applicable, should be changed to "Y."

RESPONSE: The requested change was made and other fields were also updated.

COMMENT 6: The data are adequate for acute toxicity in fish, invertebrates, and algae. Since no acute toxicity effects were noted, the toxicity was reported as >0.06 mg/L (the water solubility of the test substance). However, EPA recommends a chronic toxicity study in daphnia since the experimental log K_{ow} (6.13 at 23 °C) is greater than 4.2.

RESPONSE: While there is justification for conducting a chronic daphnia study based on the Kow, other factors must also be taken into consideration. Under the SIDS guidelines, chronic invertebrate studies are recommended if there is concern for long-term persistence in the environment. The biodegradation studies indicate significant enough biodegradation that the material would not be considered "long-term" persistent. The direct photolysis study indicates that sunlight on the water surface will break down the material. The EPIWIN modeled river half-life is less than 2 hours, thus the material will volatilize and break down photolytically in the troposphere (half-life of 4 hours). In addition, there is no known application for the material that would result in significant and consistent environmental contamination. Therefore, according to the SIDS guidance, as used by the HPV program, a chronic invertebrate cannot be strongly recommended.

Specific Comments on the Robust Summaries

COMMENT 7: *Acute toxicity.* A robust summary for an acute oral toxicity study in rats exposed to HB-40 omitted the gavage vehicle (if used).

RESPONSE: The test substance was administered undiluted. The robust summary has been corrected.

COMMENT 8: *Genetic toxicity (gene mutations).* The omitted information for the robust summary on Therminol® 66 includes the criteria for a positive result, name of the positive controls (not just identified by acronyms), and statistical analysis methods.

RESPONSE: Positive control substances were detailed and specific concentrations were stated. Formal statistical methods were not mentioned in the published article. The criteria for a positive response as given in the published paper was added to the robust summary. The robust summary now contains all relevant information given about the Ames test in the publication.

COMMENT 9: *Invertebrates*. Missing information includes the identity and the purity of the test substance. The submitter needs to clearly indicate whether the only tested concentration of 1.34 mg/L was the measured or nominal concentration.

RESPONSE: The test substance was commercial Therminol 66. As this is a complex and variable mixture a purity specification is not germane. The 1.34 mg/L was a measured concentration. The robust summary has been corrected.

COMMENT 10: *Algae*. Missing study details include the lighting conditions during the study, cell concentrations, and the frequency of measurement of cell concentrations.

RESPONSE: The requested information was found and added to the robust summary.

Environmental Defense Comments

COMMENT 11: The finished product is marketed under the name THERMINOL 66 Heat Transfer Fluid. (It is also referred to as Santosol 340 and HB-40 in the Robust Summaries submitted for this chemical, but these commercial names are not mentioned in the Test Plan.) According to the Test Plan, terphenyl, partially hydrogenated is marketed and used primarily as a heat transfer agent and to a lesser extent as a plasticizer or polymer modifier.

RESPONSE: The test plan properly states that the majority of the Partially Hydrogenated Terphenyls manufactured today are marketed as industrial heat transfer fluids under the trade name Therminol® 66 Heat Transfer Fluid. It further states that a small amount is also marketed as a plasticizer or polymer modifier. HB-40 is the brand name for this plasticizer. Santosol 340 and Santotherm 66 were similar products for which data useful to the robust summary were found. They are no longer marketed. The test plan has been corrected to identify the brand name HB-40 Plasticizer.

COMMENT 12: The absence of studies addressing Developmental Toxicity is noted in the Test Plan Matrix but is not further discussed and no additional studies are proposed. As developmental toxicity is a required SIDS endpoint, this deficiency needs to be addressed by conducting a study using the appropriate OECD guideline.

RESPONSE: An OECD 414 compliant study has been conducted and a robust summary has been added and discussed in the testing plan. See response to Comment 4.

COMMENT 13: Test Plan, page 4: The abbreviation UVCB should be identified when it first appears.

RESPONSE: The terminology UVCB means "Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials." The test plan has been changed accordingly.

COMMENT 14: According to the sponsor, in the U. S., terphenyls, partially hydrogenated are manufactured solely by Solutia Inc. and in only one plant. However, they are also manufactured abroad. It is not mentioned if they are also imported into this country.

RESPONSE: The Partially Hydrogenated Terphenyl products manufactured abroad are interchangeable with those manufactured in the US. While they are not normally imported into the US, they can be if appropriate.

COMMENT 15: According to the Test Plan, terphenyl, partially hydrogenated is marketed and used primarily as a heat transfer agent and, as such, is subject to minimal release to the environment. However, methods of transport from the producer, Solutia, Inc., to its customers are not described. In the absence of evidence to the contrary, it should be assumed that this mixture is transported in such volumes that, should an accident occur, a release of significant volumes into the environment could result. Given the resistance of this material to biodegradation, such an incident could be of concern and should be discussed.

RESPONSE: Commercial heat transfer fluids are normally shipped in 55-gallon drums or bulk trucks, as are many chemicals. Our transportation systems for all chemicals are designed to minimize both the possibility and severity of transportation incidents. Discussion of those systems is outside the scope of the HPV Chemical Challenge, and we

disagree with the comment that this product is of sufficient concern to warrant special discussion in this Test Plan.

COMMENT 16: Many of the Robust Summaries list the Test Substance "as identified by 1.1 to 1.4". We assume this refers to Sections 1.1 to 1.4 of the Robust Summaries; however, no data are provided in Sections 1.1.2 to 1.4. In other cases the Test Substance is given as "other TS", but "other TS" is not further defined.

RESPONSE: The robust summary was prepared following the conventions prescribed by IUCLID, a system that has uses other than the HPV Chemical Challenge. The sections of the IUCLID Data Set are prescribed, and standardized phrases are used in most sections. Data were not included in sections that were not appropriate for the HPV Chemical Challenge. This designation of the test substance has been changed in the robust summaries and clarified in the Test Plan to improve accuracy

COMMENT 17: Starting on page 15 and continuing to the end of the Robust Summaries, a number of sections not requested under the HPV Initiative are listed without supporting data. These sections should either be removed or relevant data provided.

RESPONSE: See response to Comment 16.

Animal Protection Organizations Comments

No responses necessary